EXHIBIT Z

a Johnson & Johnson company

To: Patrice Napoda
CC: RDCF

Biocompatibility Risk Assessment:
PROSIMA Pelvic Floor Repair System (Mint)

A biocompatibility assessment of the PROSIMA Pelvic Floor Repair System components was based on ISO 10993 part one entitled "Biological Evaluation of Medical Devices - Evaluation and Testing", and the FDA General Program Memorandum G-95.

PROSIMA consists of multiple components, which along with contact nature and duration, are summarized below. For additional composition, please refer to the attached bill of materials.

	Component	Body Contact	Contact Duration
1	PROLENE Soft Mesh	Implant	Permanent (>30 days)
2	Implant Carrier, Primary packaging	Device contact	Not applicable
3	Inserters, anterior and posterior	Externally Communicating - Tissue	Limited (<24 hr)
4	Vaginal support device	Breached/Compromised Surface	Prolonged (24 hr to 30 days)
5	Balloon assembly a - balloon, b - connector plug, extension tubing, c - adhesive, d - check valve, e – cap	Breached/Compromised Surface (a, b, c) Skin (d,e)	Limited
6	Syringe	Device contact	Not applicable

Component 1 is PROLENE Soft Mesh, which is an approved product cleared under 510k K013718[1], and has a long history of safe clinical use. Minor manufacturing modifications (ultrasonic welding, laser and ultrasonic cutting) are performed on the PROSIMA PROLENE

[1] Prolene 510k: K013718

Soft Mesh. Chemical equivalency of the welded and cut edges to naïve mesh[2] allowed for the utilization of the historical and clinical data of the predicate mesh.

Components 2 and 6 are designated as 'device contact'. The implant carrier consists of blue polyester film (currently used in PROLIFT) backed with Tyvek 1073. Both polyester film and Tyvek 1073 have acceptable device contact histories, as does the PETG Blue used for the primary packaging. The syringe, supplied by Becton Dickson, also has acceptable historical data[3], and is a commercially available product.

Component 3, the inserters are comprised of 304 ¼ hardness Stainless Steel and Dow Calibre 2061-15 PC (FC850122). This stainless steel is typical of many general use surgical tools and compliant with ASTM F899-02. Dow Calibre 2061-15 PC (FC850122) was previously characterized by Ethicon[4] and is used for handles on various instruments in GYNECARE TVT Products. As such, further biocompatibility testing was not conducted on these components.

Component 4, the vaginal support device, consists of Nusil Silopren LSR 4050, Pantone 428C (gray). Nusil supplied cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogenicity and 7-day intramuscular implantation data on the natural (unpigmented) steam sterilized material[5]. Chemical equivalence of the natural and gray materials was demonstrated[6], allowing the use of the manufacture's data. To address any potential concerns resulting from ethylene oxide sterilization of the material, EO residuals will be determined during sterilization validation, and must be acceptable as defined in the ISO 10093:7 standard.

In addition, Ethicon conducted a 30-day vaginal implantation study of the ethylene oxide sterilized gray material to demonstrate safety of the intended clinical usage:

Accession #	Description	Result
06-0326	Vaginal Implantation in Rabbits, VSD material, gray	Pass

The Silopren LSR 4050, Pantone 428C (gray) did not exhibit evidence of irritation when in contact with vaginal mucosa for 30 days.

Component 5, the balloon assembly, was tested by Ethicon as a unit. The following assays were performed:

Accession #	Description	Result
05-0558	Cytotoxicity (MEM), Balloon Assembly	Pass
05-0559	Sensitization, Local Lymph Node Assay, Balloon Assembly, Saline and DMSO	Pass
05-0560	Intracutaneous Reactivity, Balloon Assembly, Saline and Sesame Oil	Pass
05-0561	Vaginal Irritation, Balloon Assembly, Saline and Sesame Oil	Pass
05-0562	Acute System Toxicity, Balloon Assembly, Saline and Sesame Oil	Pass
06-0182	Material Mediated Pyrogenicity, Balloon Assembly	Pass

[2] Chen, K. Extractables/Leachables of the Ultrasonic Welded Polypropylene Mesh Pockets for Project Mint. RCPC-111606-KC. 2006.
[3] Eaker, D. 50ml Plastipak Syringes. 2006
[4] Hutchinson, R. Biocompatibility summary of Calibre 2061-15 FC850122, sterilized by cobalt and ETO. 2001.
[5] Savidge, S. LSR 4050 Biocompatibility Summary. 2006.
[6] Chen, K. Extractables/Leachables of the Silicon Splint Materials Containing Colorant Pantone 428C for Project Mint. RCPC-111506-KC. 2006.

06-0361	Cytotoxicity (MEM), Cap & Tether	Pass
06-0362	Sensitization, Local Lymph Node Assay, Cap & Tether, Saline and DMSO	Pass
06-0363	Intracutaneous Reactivity, Cap & Tether, Saline and Sesame Oil	Pass

Based on the historical and current study data listed above, the components of the PROSIMA Pelvic Floor Repair System pose no risk to human health.

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Date: 12/27/06

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To: Sandy Savidge
From: Vincenza Zaddem
Subject: Biocompatibility BOM for EWH&U Project MINT
Date: November 30, 2006

The purpose of this memo is to document the materials that are being considered by Project MINT for the PROSIMA Pelvic Floor Repair Systems. The three Procedural Kits consist of the following devices:

PROSIMA ANTERIOR PELVIC FLOOR REPAIR SYSTEM
Contents: 1 Mesh Implant
1 VSD-Balloon Assembly
1 Anterior Inserter
1 Syringe

PROSIMA POSTERIOR PELVIC FLOOR REPAIR SYSTEM
Contents: 1 Mesh Implant
1 VSD-Balloon Assembly
1 Posterior Inserter
1 Syringe

PROSIMA COMBINED PELVIC FLOOR REPAIR SYSTEM
Contents: 2 Mesh Implants
1 VSD-Balloon Assembly
1 Anterior Inserter
1 Posterior Inserter
1 Syringe

MINT Components Breakdown	
1	Mesh Implant-Implant Carrier Assembly
1a	Mesh Implant
1b	Implant Carrier
2	VSD-Balloon Assembly
2a	VSD
2b	Balloon Assembly
2b-i	Check Valve
2b-ii	Tubing
2b-iii	Connector Plug
2b-iv	Balloon
2b-v	Adhesive
2b-vi	Tethered Cap
3	Anterior Inserter
4	Posterior Inserter
5	Syringe
6	Primary Packaging

Mesh Implants:
Ethicon Sárl manufactures the finished Mesh Implant and assembles the Mesh Implant into an Implant Carrier. The Mesh Implant shape will be cut from GYNEMESH PS by laser process, and pockets will be created on the ends of each strap by folding, and ultrasonic welding and cutting.

VSD:
The VSD (Vaginal Support Device) is fabricated at Silcotech by liquid injection molding. The VSD is then bulk shipped to Ethicon Sárl for assembly with balloon and final packaging.

Balloon:
Polyzen fabricates the balloon subassembly by RF welding flat sheets of polymer, cutting, and inverting, and then assembling to an inflation line. The inflation line consists of a connector plug (injection molded at Polyzen), tubing (extruded by A.P. Extrusion), check valve (BBraun), and cap (DirectMed). The plug and check valve are glued to the tube with U.V. epoxy (Dymax). The cap tether is fit over the valve's luer lugs. The finished balloon assembly is supplied in bulk to Ethicon Sárl for assembly with VSD. A reusable assembly tool will be used to facilitate assembly of balloon to VSD at Ethicon Sárl.

Anterior Inserter:
Sored S.A. stamps, deburrs, forms, and passivates the metal shaft and then ships to Gueissaz for overmolding the plastic handle on to the shaft. The finished Anterior Inserter is bulk shipped back to Sored for inspection and then bulk shipped to Ethicon Sárl for final packaging.

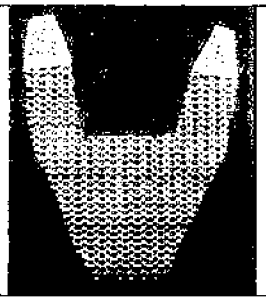
Posterior Inserter:
Sored S.A. stamps, deburrs, and passivates the metal shaft and then ships to Gueissaz for overmolding the plastic around the distal end of the shaft. The finished Posterior Inserter is bulk shipped back to Sored for inspection and then bulk shipped to Ethicon Sárl for final packaging.

Syringe:
The 50-mL syringe is an off-the-shelf part, pre-packaged, EO pre-sterilized, and shipped to Ethicon Sárl for inclusion in the kit. This syringe has graduated markings for capacity up to 60-mL.

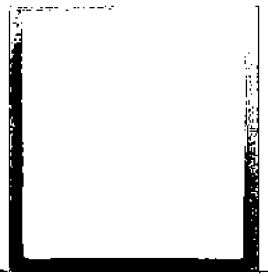
Sterilization:
All devices are sterilized by Ethylene Oxide (using a maximum dose version of the TVT family cycle).

1. Mesh Implant-Card Assembly

1a. Mesh Implant

PICTURE	PART NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21005 (Ethicon Sárl)	Mesh Implant	Prolene, Polypropylene / Ethicon, Cornelia	N/A	Implant Device - Tissue/Bone	Permanent, >30 Days	Same materia used in Gynemesh PS product; contact with Inserter

1b. Implant Carrier

PICTURE	PART NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21035 (Mangar)	Film	M1811 (Clear, 1.5 Mil Copolymer, same as used in Prolift implant carrier)	N/A	Device Contact	N/A	contact with Me Implant
N/A	N/A	Backing	Tyvek 1073b uncoated, unprinted / Dupont	N/A	Device Contact	N/A	contact with Me Implant

2. VSD-Balloon Assembly

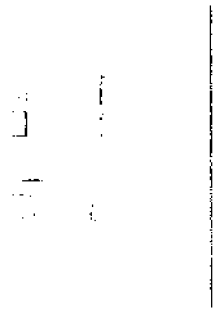
2a. VSD

PICTURE	PART NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21026 (Ethicon Sárl)	VSD	Silicone Silopren LSR4050, Shore 50A (GE Bayer) Pantone 428C (med grey) / Silcotech	Closest LSR 4070	Breached/Compromised Surface	Temporary, 1>x>30 Days	contact with Balloon Assembly

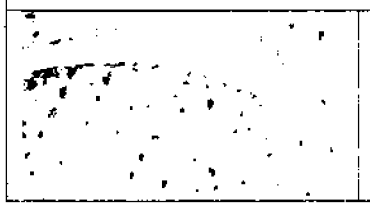
2b. Balloon

PICTURE	PART NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21024 (Ethicon Sárl)	Balloon Assembly	see Balloon sub-components	N/A	Breached/Compromised Surface	Limited, < 24 Hours	Tested as an assembly

2b-i. Check Valve

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	A-561-1 (B.Braun)	SAFSITE® Needle-Free Valve, Female Luer Lock to Male Luer Slip	Housing: Bayer Makrolon Polycarbonate RXI1805-451118, Violet Plug: Bayer Makrolon Polycarbonate RXI1805-451118, compounded with LEX-506313JLDC, Powder Blue Membrane: Dow Corning Silastic RX 50 CT, natural / B.Braun #S5401010SN	N/A	N/A	N/A	OTS item; contact with Syringe and Patient Thigh

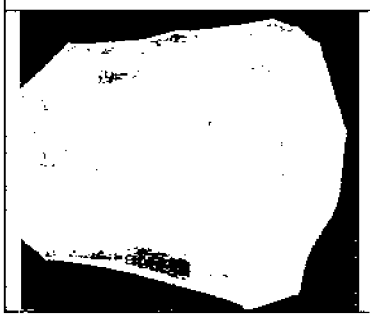
2b-ii. Tubing

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• DP9672-20 (Polyzen)	Tubing	Pellethane 2363-80AE, natural / A. P. Extrusion	N/A	N/A	N/A	contact with Valve, Plug, an Patient Thigh

2b-iii. Connector Plug

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• DP9673-10 (Polyzen)	Connector Plug	Pellethane 2363-80AE, natural / Polyzen	N/A	N/A	N/A	contact with Balloon Film, Tubing, and VSI

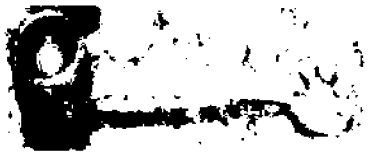
2b-iv. Balloon Film

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• DP9673-2A (Polyzen)	Balloon Film	Polyurethane: TSP 1065, natural / Polyzen	N/A	N/A	N/A	contact with Plu and VSD

2b-v. Adhesive

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
N/A	N/A	N/A	U.V. Curing Urethane Oligomer/ Methacrylate Monomer Blend Color: clear/light amber / Dymax # 204-CTH	N/A	N/A	N/A	contact with Tubing, Plug, Val

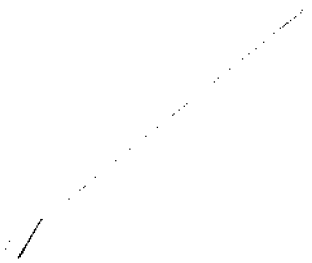
2b-vi. Tethered Cap

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	N/A	Tethered Male Luer Cap, Non-vented	High Density Polyethylene, Blue / DirectMed #CA-065	N/A	N/A	N/A	Contact with Valve

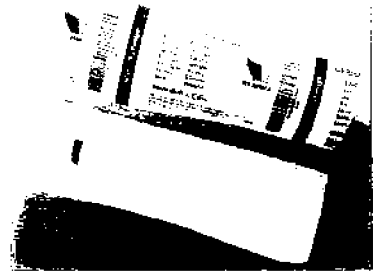
3. Anterior Inserter

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21020 (Ethicon Sárl)	Anterior Inserter	Shaft: 304 stainless steel (1/4 hard) / Sored S.A Overmold: Dow Calibre 2061-15 PC White (FC850122), polycarbonate / Gueissaz	N/A	External Communication - Tissue/Bone/Dentin	Limited, < 24 hours	Also contact with Mesh Implant

4. Posterior Inserter

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21021 (Ethicon Sárl)	Posterior Inserter	Shaft: 304 stainless steel (1/2 hard) / Sored S.A Overmold: Dow Calibre 2061-15 PC White (FC850122), polycarbonate / Andre Gueissaz & Cie S.A.	N/A	External Communication - Tissue/Bone/Dentin	Limited, < 24 hours	Also contact with Mesh Implant

5. Syringe

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
	• P21028 (Ethicon Sárl)	50-mL BD Plastipak Luer-Lok syringe	- Synthetic Polyisoprene (West 7448) - Polypropylene (Basell PP348P) - Polypropylene (Basell HP570R) - Silicone Lubricant (Dow Corning 360) / BD #300865	N/A	N/A	N/A	OTS item; contact with Balloon Assembly; the syringe has 60-cc capacity

6. Primary Kit Packaging

PICTURE	DWG NO.	NAME	MATERIAL / SUPPLIER	J&J BIOCOMP DATABASE REPORT REF #	BODY CONTACT	CONTACT DURATION	NOTES
N/A	▪ P21030 (Ethicon Sárl)	Exterior Thermoform Tray (for Anterior, Posterior, Combined Kits)	PETG Blue / Cartolux- Thiers	N/A	Device Contact	N/A	Primary Packaging Device Contact
N/A	▪ P21032 ▪ P21034 (Ethicon Sárl)	- Workstation - Retainer Lid (for Anterior, Posterior, Combined Kits)	PETG Blue / Cartolux- Thiers	N/A	Device Contact	N/A	Primary Packaging Device Contact
N/A	▪ P21040 ▪ P21041 ▪ P21042 (Ethicon Sárl)	Tyvek Lid - Anterior Kit - Posterior Kit - Combined Kit	Tyvek / Dupont	N/A	Device Contact	N/A	Primary Packaging Device Contact

[DOCUMENT END]